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Clinical evaluations of resin-modified glass-ionomer restorations

Sharanbir K. Sidhu*

Adult Oral Health, Queen Mary University of London, Barts & The London School of Medicine and Dentistry, Institute of Dentistry, Turner Street, London E1 2AD, UK

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ABSTRACT

Objectives. This paper collates some of the existing data on the clinical evaluations of resin-modified glass-ionomer cements (RMGICs) since their introduction two decades ago.

Methods. The relevant literature was considered and data reviewed under the headings of retention, marginal characteristics, material deterioration, secondary caries, color stability, as well as pulpal and biological effects.

Results. The retention for RMGICs is generally good, with an annual failure rate over 13 years reported as being under 3%. However, more data is required on their performance in carious situations. Regarding marginal characteristics, they exhibit margins that are likely to deteriorate over time. From the limited data on the surface characteristics, they appear to exhibit some wear and loss of anatomic form, particularly in the mid to long term. Despite the fact that the studies reviewed for secondary caries varied in the initial caries status of lesions restored, the overwhelming conclusion is that this does not seem to be a problem. While their initial color match may be favorable, it appears that they change over time and may not be color stable. In the absence of more clinical data, it is difficult to draw conclusions on the pulpal and biological effects. The existing information primarily reports postoperative sensitivity, which fortunately does not seem to be an issue with RMGICs, and limited histopathology of the pulp, with mixed opinions.

Significance. The RMGICs appear to perform well in terms of retention, and secondary caries as well as postoperative sensitivity are not a problem. However, this is not necessarily true of their marginal characteristics, surface properties and color stability. More and long-term clinical research is required to establish compelling evidence of their behavior, particularly in terms of retention in carious cavities, surface properties and biological effects.

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1. Introduction

The quest for an ideal restorative dental material has been ongoing and this is nowhere more evident than in the realm of adhesive materials. Tooth-colored adhesive materials include the glass-ionomer cements (GICs), which were

invented by Wilson and Kent in 1969 at the Laboratory of the Government Chemist in London, UK [1]. As with most other materials, they too have been subjected to waves of improvements and developments. One such development was the introduction of the resin-modified glass-ionomer cement (RMGIC) materials patented in the late 1980s [2,3]. This innovation was an attempt to help overcome the problems

* Tel.: +44 0 20 7882 8617; fax: +44 0 20 7882 7064.

E-mail address: s.k.sidhu@qmul.ac.uk.

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traditionally associated with the conventional GIC materials, i.e. moisture sensitivity and low physical properties (particularly their early mechanical strength). The RMGICs were thought of as an improvement over the original materials while still maintaining the clinical advantages of the traditional GICs, such as adhesion and fluoride release offering some protection against caries. In essence, the RMGICs are glass-ionomer cements with the incorporation of a small quantity of monomers as well as initiators involved in the polymerization reaction. Rapid acceptance of these materials by the dental profession saw subsequent similar materials appearing in the marketplace which were variations of the same theme. However, these latter materials are not considered as true GICs as they do not fulfill the requirements of a GIC of having a typical acid-based glass-ionomer reaction, unlike the RMGICs which are considered as GICs. By definition, the RMGICs contain a basic ion-leachable glass, a water-soluble polymeric acid, organic monomer/s and an initiator system [4].

2. Clinical evaluations

The ultimate success, or otherwise, of a material is indicated by its longevity in the oral environment. As the initial laboratory tests of new materials do not always reveal their full limitations or assets, clinical data are essential to confirm their characteristics by solid empirical evidence. Unfortunately, at the present time, there is no consensus on the desired or ideal length of time of a clinical study to accurately predict the performance or life expectancy of restorative materials. Differences between studies often make comparisons difficult; the data from one may not be easily compared with another. In addition, sample size is a perennial issue and it is often not possible to extrapolate trends from small samples. Nevertheless, information gleaned from continual assessments is important in the hope that cumulative information adds to the body of evidence to help in making informed decisions regarding options for restoration. As a "major undertaking for general practitioners is the provision and assessment of dental restorations" [5], observations in

clinical practice lend some valuable evidence if interpreted appropriately.

The RMGICs have been around for approximately twenty years now. They are used today in a variety of clinical situations, notably as liners/bases, luting agents and restorative materials. After two decades of use, it is reasonable to expect some level of evidence regarding their clinical performance. What has our experience in the past twenty years shown of these materials? Is there sufficient clinical information?

This paper collates some of the available data on the clinical evaluations of restorative RMGIC materials. It is not intended to be a systematic review of the subject. The relevant literature was considered and data reviewed under the headings of retention, marginal characteristics, material deterioration, secondary caries, color stability, as well as pulpal and biological effects.

2.1. Retention

Modern adhesive techniques are based on the premise that materials adhere to tooth structure and are retained within a cavity. Hence, retention is one of the most important criteria often used to assess the longevity of a restorative material. It is also one of the most commonly observed physical properties clinically.

One of the earliest clinical studies on RMGICs evaluated Class V abrasion lesions in 13 patients restored with one of three RMGICs; the retention rate at one year was found to be excellent (100%) [6]. Subsequently, in another study the retention of one RMGIC at 18 months was found to be 95% [7]. A more extensive study revealed no loss of RMGIC restorations in similar cavities even after two years [8]. A large 18-month clinical trial of two commercially available (and one experimental) RMGICs confirmed the excellent retention, although the marginal seal remained a problem as cervical defects were noted as early as at the six-month recall [9]. The aforementioned studies were conducted on non-carious Class V type of abrasion cavities. However, a study assessing restorations in carious as well as non-carious Class V cavities over three years found a survival rate of 93.3% for one RMGIC and 85.7% for

Table 1 – Clinical observations on retention rates of RMGICs from studies over one to 13 years, showing retention rates of 85.7–100%.

Investigators	Number of restorations	Number of RMGICs	Types of cavities	Results: retention	Duration of study
Maneenut and Tyas (1995)	60	3	Class V, abrasion	100% retention	1 year
Neo et al. (1996)	21	1	Non-carious, cervical	95% retention	18 months
Abdalla and Alhadainy (1997)	80	3	Class V, abrasion	100% retention	2 years
Gladys et al. (1998)	122	3 ^a	Class V, abrasion/erosion	100% retention	18 months
Folwaczny et al. (2001)	82	2	Class V, carious and non-carious	93.3% and 85.7% survival	3 years
Ermis (2002)	20	1	Abrasion/erosion	95% retention	2 years
Loguercio et al. (2003)	16	1	Class V, non-carious	93% retention	5 years
Van Dijken and Pallesen (2008)	49	1	Non-carious, cervical	Lowest annual failure rate of 2.7%	13 years

^a This included 2 commercial products and 1 experimental RMGIC.

Table 2 – Clinical results of marginal characteristics of RMGICs up to five years, showing differences in observations, but in general there was deterioration in both marginal adaptation and the presence of marginal discoloration.

Investigators	Number of restorations	Number of RMGICs	Types of cavities	Marginal characteristics	Duration of study
Neo et al. (1996)	21	1	Non-cariou, cervical	Marginal adaptation: 24% Alpha rating, marginal discoloration: 76% Alpha rating (USPHS criteria)	18 months
Gladys et al. (1998)	122	3 ^a	Class V, abrasion/erosion	Significantly deteriorated from 6 months; mainly small defects at the cervical margins	18 months
Folwaczny et al. (2001)	82	2	Class V, primary and secondary carious/non-cariou	Marginal integrity (55–61% Alpha) and discoloration (48–71% Alpha) worst with RMGICs	3 years
Loguercio et al. (2003)	16	1	Class V, non-cariou	Both marginal adaptation and discoloration: 84.6% Alpha rating (USPHS criteria)	5 years

^a This included 2 commercial products and 1 experimental RMGIC.

another RMGIC [10]. Whether the presence of carious lesions within that study lowered the retention rate is a tempting idea but difficult to confirm.

A small study comparing the clinical performance of several polyacid-modified composite resins with that of one RMGIC in non-cariou abrasion lesions found that there was no statistically significant difference between the materials, with the RMGIC's retention rate being 95% at two years [11]. Similar findings were observed over five years with a retention rate of 93% for the same RMGIC [12]. The longest assessment of these materials is provided in a 13-year evaluation of different adhesive systems which found the RMGIC to give among the best retention and lowest annual failure rate [13]. It could be argued that as the study was performed on non-cariou cervical lesions without enamel involvement, this gave the RMGIC a perceived advantage. However, it does not detract from the fact that the long period of observation highlighted the good performance of the RMGIC assessed and should not be overlooked.

In general, there does not seem to be a huge variation in retention rates between the studies reviewed in spite of differences such as sample sizes, products used and duration of clinical observation (Table 1). The retention rates appear to be better in non-cariou lesions and there is not enough information regarding their performance in carious situations. Although the latter point reflects the problems associated with clinical studies on carious cavities, it nevertheless highlights the need for more information regarding the materials' performance in such lesions.

2.2. Marginal characteristics

Evaluations of the marginal characteristics of a restoration over time are used as an indicator of the microleakage potential and maintenance or deterioration of esthetics. These characteristics may be assessed using parameters such as marginal integrity, adaptation or discoloration, either on their own or in combination.

One such evaluation of RMGICs found that the marginal adaptation was poor at 18 months (24% Alpha rating using

USPHS criteria) and that marginal discoloration was apparent in some restorations (76% Alpha) [7]. Another study found that margins that were perfect at restoration placement significantly deteriorated after six months [9]. The margins either stabilized or showed a steady decline over the next 18 months, with the discrepancies being mainly small defects at the cervical margins of Class V lesions [9]. These restorations concomitantly displayed superficial localized discoloration at the margins, although one RMGIC showed the least discoloration and was significantly better throughout the whole evaluation period than another one being assessed. Other researchers found that the marginal integrity and discoloration over three years was the worst with the RMGICs compared to a composite resin and a polyacid-modified composite resin [10]. In contrast, some researchers observed that one RMGIC performed significantly better than a polyacid-modified composite resin after five years in non-cariou Class V restorations [12]. The criteria assessed were marginal adaptation (84.6% rated Alpha using USPHS criteria, 15.4% Bravo) and marginal discoloration (84.6% rated Alpha, rest rated Bravo). A summary of these studies is given in Table 2.

It is evident that there is considerable variation in the results for marginal characteristics of the RMGICs. However, it is important to bear in mind that direct comparisons may not be made with these studies as they vary in terms of the type of margins, placement of margins (whether on enamel or dentin), RMGICs used, as well as initial caries status of the cavities. Certainly the earlier studies appear to have worse results than the later ones. This may be due to different materials used or product evolution as they are constantly being reformulated and modified by manufacturers to improve properties. Nevertheless, when the available data is reviewed in the light of marginal properties, it is reasonable to conclude that the RMGICs exhibit margins that are likely to deteriorate over time.

2.3. Material deterioration

Loss of anatomic form and wear could be interpreted as being consistent with deterioration of a material and may affect

Table 3 – Observations of the surface texture and anatomic contours in vivo appear to indicate better results in the shorter term, but a decline over a longer period.

Investigators	Number of restorations	Number of RMGICs	Types of cavities	Material deterioration	Duration of study
Neo et al. (1996)	21	1	Non-cariou, cervical	Anatomic form: 86% Alpha rating (USPHS criteria)	18 months
Folwaczny et al. (2001)	82	2	Class V, primary and secondary carious/non-cariou	Surface texture (9% and 16% Alpha rating); anatomic contours (35% and 39% Alpha rating)	3 years
Loguercio et al. (2003)	16	1	Class V, non-cariou	86% Bravo rating for surface texture; 87.5% Alpha rating for anatomic form	5 years

its longevity. In the short-term, the anatomic form of these materials appears reasonable (86% Alpha rating) [7]. However, over a longer period, the RMGICs do not appear to perform well. In a three-year study, the surface texture and contours of restorations using two RMGICs were found to be the poorest compared with those of a composite resin and a polyacid-modified composite resin; only 9% or 16% were rated Alpha for surface texture while only 35% or 39% were rated Alpha for anatomical contours [10]. In contrast, in a subsequent report, only 12.5% of RMGIC restorations showed loss of anatomical form (rated Bravo; 87.5% rated Alpha) after five years [12]. However, 86% of the restorations were rated Bravo for surface texture in the same study. These studies are summarized in Table 3.

It is reasonable to conclude from the limited data that the RMGICs exhibit some loss of anatomic form and surface wear, particularly in the mid to long term.

2.4. Secondary caries

The detection of secondary caries after placement of a restoration in a cavity may be due to any one or more of several factors involving the material, the patient, the cavity and the operator or technique. In the absence of clearly defining factors involved in the occurrence or recurrence of the carious process, the presence of secondary caries is often interpreted as a function of the material properties if all other confounding factors are kept to a minimum. Cross comparison between

studies is difficult but gives an idea of the general caries potential of the material.

In a study to establish the clinical performance of an RMGIC in non-cariou cervical lesions, there was no secondary caries detected after 18 months [7]. This observation was similar to another report in which no recurrence of caries was found at the one and two year recalls in Class V carious lesions [14]. The absence of secondary caries was confirmed later by researchers evaluating RMGICs in mixed carious and non-cariou Class V cavities over three years [10], as well as by others observing Class V non-cariou RMGIC restorations over five years [12]. In a separate study using an RMGIC in “open-sandwich” restorations in large Class II cavities, only one out of 239 restorations showed secondary caries after three years, although 43% of the patients were considered caries-risk patients [15]. A summary of these studies is presented in Table 4.

The studies reviewed above varied in the type of lesions restored, i.e. whether carious or not to begin with, and other factors that could be implicated in caries. Despite this, the overwhelming conclusion is that these materials do not appear to encourage, promote or induce the development of caries for as long as up to five years. Interestingly, this is in spite of the apparent deterioration of marginal adaptation over time (see Section 2.2), which would ordinarily imply microleakage potential and all the eventual sequelae including secondary caries. Perhaps this would have occurred in the fullness of time if the relevant studies were extended.

Table 4 – A summary of the clinical assessment of secondary caries development which indicates that this does not seem to be a problem with the RMGICs.

Investigators	Number of restorations	Number of RMGICs	Types of cavities	Secondary caries	Duration of study
Neo et al. (1996)	21	1	Non-cariou, cervical	No secondary caries observed	18 months
Abdalla et al. (1997)	60	2	Class V, carious	No secondary caries	2 years
van Dijken et al. (1999)	274	1	Class II, “open-sandwich”, primary caries and replacement restorations	Only 1 out of 239 restorations showed recurrent caries	3 years
Folwaczny et al. (2001)	82	2	Class V, carious and non-cariou	No secondary caries	3 years
Loguercio et al. (2003)	16	1	Class V, non-cariou	No secondary caries	5 years

Table 5 – Clinical studies involving observations of color stability showing poor overall results in terms of shade match.

Investigators	Number of restorations	Number of RMGICs	Types of cavities	Color stability	Duration of study
Maneenut and Tyas (1995)	60	3	Class V, abrasion	Significant darkening for 1 RMGIC	1 year
Neo et al. (1996)	21	1	Non-carious, cervical	48% Alpha rating (USPHS criteria) comparable to the resin composites	18 months
Folwaczny et al. (2001)	82	2	Class V, primary and secondary caries and non-carious lesions	Poorest shade match (58% and 40% Alpha rating)	3 years
Loguercio et al. (2003)	16	1	Class V, non-carious	86% Bravo rating	5 years

Table 6 – Studies on longevity of RMGICs showing postoperative sensitivity were either non-existent or minimal, while pulpal reactions were mixed.

Investigators	Number of restorations	Number of RMGICs	Types of cavities	Pulpal and biological effects	Duration of study
van Dijken et al. (1999)	274	1	Class II, “open-sandwich”, primary caries and replacement restorations	Postoperative sensitivity in 9 out of 274 restorations	3 years
van Dijken (1999)	36	1	Large Class III	No postoperative sensitivity and loss of vitality	5 years
do Nascimento et al. (2000)	34	1	Buccal Class V	Inflammatory reaction with a lack of dentin bridge formed	5–300 days
Tarim et al. (1998)	112	1	Class V	Acceptable biocompatibility in exposed and non-exposed cavities	6–97days
Felton et al. (1991)	71	1	Class V	Excellent pulp response	7 and 35 days

2.5. Color stability

The color stability of a tooth-colored restorative material is a crucial element of esthetics. One of the earlier studies found a significant darkening in the color of one RMGIC but no significant change in the other two materials after a year [6], while another found the color match to be less than satisfactory after 18 months in service (48% Alpha rating) [7]. This was later confirmed by other researchers who found that a considerable number of the restorations (using two RMGICs) were rated Bravo regarding the “shade match” at three years [10]. Similarly, in a subsequent report, 86% of restorations were rated Bravo at five years [12] (Table 5).

While the initial color match may have been favorable relative to tooth structure, it appears that these materials change over time. This may be related to the surface changes within the materials as manifested in the form of loss of anatomic contour and wear (see Section 2.3).

2.6. Pulpal and biological effects

The pulpal and biological effects of a material are fundamental to its usage, particularly in vital teeth. Although materials often undergo rigorous testing by the manufacturers in order to comply with regulations for use in the human body, the effects of these may not be borne out until later. In addition, laboratory tests do not always reveal the full effects.

There is a dearth of clinical information on the RMGICs in this aspect.

With regards to postoperative sensitivity, one report found that only nine out of 274 restorations caused sensitivity in “open-sandwich” restorations [15] (Table 6). In large Class III situations, no postoperative sensitivity or loss of pulp vitality was recorded over five years [16].

In an evaluation of pulp-capping materials, a commercial RMGIC was found to trigger a persistent inflammatory reaction [17]. In contrast, an animal study on exposed as well as non-exposed pulps in monkeys showed acceptable biological compatibility of the RMGIC for this application in both scenarios [18], confirming the results of an earlier study using an experimental RMGIC [19].

A recent review of the literature on biocompatibility of the RMGICs used in dentistry revealed mainly *in vitro* data; the authors concluded that the RMGICs cannot be considered biocompatible to the same extent as conventional glass-ionomers [20]. In the absence of more clinical data, it is difficult to arrive at a definite conclusion regarding the pulpal and biological effects. The existing information only reports postoperative sensitivity, which fortunately does not seem to be an issue with RMGICs, and limited histopathology of the pulp, with mixed opinions. In the meantime, the most useful concept to bear in mind is to pay every attention to detail in the restorative procedure to help minimize any harmful consequences to the tooth.

3. Conclusion

This paper reviewed some of the existing literature on the clinical performance of RMGICs. The drawbacks of comparisons between studies are clinical and perceptual variations. Nevertheless, they provide a useful, albeit sometimes limited, resource. It is also unfortunate that there is little information about some aspects of clinical performance to be able to understand how successful, or otherwise, restorative procedures with RMGICs are.

In general, the RMGICs appear to perform well in terms of retention. Secondary caries as well as postoperative sensitivity are not a problem. However, this is not necessarily true of their marginal characteristics, surface properties and color stability. More as well as long-term clinical research is required to establish compelling evidence of their behavior, particularly in terms of retention in carious cavities, surface properties and biological effects.

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